NOV 0 2 2001

K012531

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:
Mr. Joel Kent

DATE:
August 3, 2001

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx

COMMON NAME:

Medical device data converter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Transducer Signal amplifier and conditioner (per 21 CFR 870.2060)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The S/5™ Device Interfacing Solution is substantially equivalent in safety and effectiveness to the legally marketed (predicate) AS/3 Interface Board, B-INT (K935477).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Device Interfacing Solution (DIS) has the following key components: Device specific converter module, device specific cable, bus cable to another DIS converter module, if needed, and Datex-Ohmeda monitor bus cable.

External devices are connected to the monitoring system by using converter modules that handle the communication between the device and S/5 monitoring system. These DIS converter modules convert the data coming from the connected device to a format that can be utilized in the S/5 Anesthesia Monitor, S/5 Critical Care Monitor, S/5 Compact Anesthesia Monitor, or S/5 Compact Critical Care Monitor.

The DIS converter module is connected to to the socket at the rear of the Datex-Ohmeda monitor with a bus cable. The bus cable is also used for connecting DIS converter modules to each other. Specific modules can be connected to the different type of external devices. Up to ten DIS converter modules can be connected in series. Each external device has its own specific DIS converter module that can be used only with that device. One DIS converter module is needed for interfacing one external device.

The use of a DIS system consists of making physical connections: connecting external devices to DIS and linking DIS modules together to make a complete bus, and sending the converted data to the S/5 monitoring system. The user can then select the source of measurement data for physiologic parameters displayed in the Datex-Ohmeda monitor.

The Device Interfacing Solution supports interfacing of the following device categories: ventilators/anesthesia machines, stand-alone monitors, blood gas analyzers and heart-lung machines.

The Device Interfacing Solution can interface numerical, waveform and event type of data from the external device. Alarms are not transferred.

Interfaced data can be displayed on the monitor screen, trended, printed and used for record keeping purposes. Also, interfaced physiologic data is sent to the network to be viewed at the Central station monitor.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda S/5 Device Interfacing Solution, DIS, is intended to be used with a Datex-Ohmeda monitoring systems for transfering data from external devices.

The Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx is indicated for data transfer from ventilators/anesthesia machines, stand-alone monitors, blood gas analyzers and heart-lung machines to Datex-Ohmeda bedside monitors for displaying and patient care information purposes. The devices are indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The S/5™ Device Interfacing Solution is substantially equivalent in safety and effectiveness to the legally marketed (predicate) AS/3 Interface Board, B-INT (K935477).

The S/5™ Device Interfacing Solution (later referred to as DIS) is an additional part of a Datex-Ohmeda modular S/5™ monitoring system. The Device Interfacing Solution enables connection of external medical bedside devices such as stand-alone monitors, ventilators/anesthesia machines, blood gas analyzers and heart-lung machines to the monitoring systems.

The DIS does not perform any physiological measurements itself. It receives data from connected external devices and transfers it in to the S/5™ monitoring system. The Datex-Ohmeda S/5™ monitor displays, trends and uses data for calculations and transfers it to the record keeping system and network accordingly. In terms of overall function, the S/5™ Device Interfacing Solution connected to an S/5™ monitoring systems is substantially equivalent in safety and effectiveness to the Datex-Ohmeda AS/3™ Interface Board, B-INT (K935477).

The S/5™ Device Interfacing Solution, in terms of general function is identical to its predicate AS/3™ Interfacing board, B-INT (K935477). The S/5™ DIS simply extends the capability to interface more devices simultaneously, allows interfacing of different device types and also allows transfer of event type of data.

The concept of the S/5™ Device Interfacing Solution is the same as the predicate but the implementation differs slightly.

The predicate AS/3™ Interfacing board, B-INT (K935477) is a circuit board located in the frame of the monitor. It interfaces external medical devices such as monitors and anesthesia machines. One B-INT board includes drivers for the whole device library. The predicate B-INT is able to transfer numerical, waveform and alarm data from the interfaced device.

The S/5™ Device Interfacing Solution is a module that can be placed close to the interfaced external device. It interfaces external medical devices such as monitors, ventilators, anesthesia machines, blood gas analyzers and heart-lung machines. The module is device specific: a separate DIS module is needed to interface each external device. The DIS is able to transfer numerical, waveform and event type of data such as ventilator settings, laboratory results and heart-lung machine settings.

The S/5™ Device Interfacing Solution does not transfer alarms.

In summary, the S/5™ Device Interfacing Solution described in this submission is substantially equivalent to the predicate device.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- EN 60601-1:1990 + Amdt 1:1993 + Amdt 2:1995 + Amdt 3:1996
- Medical electrical equipment Part 1: General requirements for safety
- IEC 60601-1:1988 +Amdt 1:1991 + Amdt 2:1995
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 + Amdt 2:1998
- UL 2601-1,October 24, 1997
- IEC 60601-1-2:1993
- EN 980: 1996
- EN 1041 1998
- EN 60529

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex Ohmeda
86 Pilgrim Road
Needham, MA 02492

Re: K012531
Trade Name: Datex-Ohmeda S/5™ Device Interfacing Solution N-DISxxxx
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitors (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: 74 MSX
Dated: August 3, 2001
Received: August 6, 2001

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

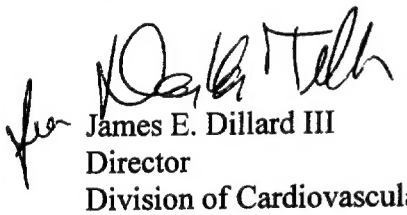
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012531

NOV 0 2 2001

Device Name: Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx

The Datex-Ohmeda S/5 Device Interfacing Solution, N-DISxxxx is indicated for data transfer from ventilators/anesthesia machines, stand-alone monitors, blood gas analyzers and heart-lung machines to Datex-Ohmeda bedside monitors for displaying and patient care information purposes.

The devices are indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012531